Vaccine Identification Standards Initiative (VISI)

Summary of Conference Call
January 14, 1999
3:00 PM - 5:00 PM EST

CALL PARTICIPANTS

Dr. Bruce Weniger (moderator)	National Immunization Program/CDC
Bindi Patel	National Immunization Program/CDC
Dinny Smith	Pharmacy Division/Texas Department of Health
Gene Trautman	Pharmacy Division/Texas Department of Health
Gina Butler-Galliera	SmithKline Beecham Pharmaceuticals
Katie Maher	Merck Vaccine Division
Cindy Dickson	Merck Vaccine Division
Ron Filipski	Pasteur Merieux Connaught
Robert Rosofsky	Massachusetts Department of Health
Del Carvell	Georgia Immunization Program
Carol Krueger	Center for Biologics Evaluation and Research/FDA
Dr. Richard Zimmerman	American Academy of Family Physicians

SUMMARY

VISI Introductions

Dr. Bruce Weniger welcomed all VISI participants and asked everyone to identify themselves. He also introduced Ms. Bindi Patel, a vaccine development fellow, who will be replacing Josh Schwartz.

Background to Draft Prototypes

Before the conference call, VISI participants were urged to visit the VISI website, http://www.cdc.gov/nip/visi and review the draft prototypes. These were discussed, as follows.

Dr. Weniger began by introducing the draft prototypes and asked VISI participants if they were able to access the website. Only one individual was not able to access the VISI website.

Dr. Weniger asked VISI participants if disseminating this information on the internet was a good method of communication. All participants agreed.

Dr. Weniger also explained that much of the rationale for the draft prototypes has not been completed. However, he anticipated this to be done in the near future and will provide this information to all VISI participants when completed.

Discussion of Draft Prototypes

Comments on the prototype ***Bar-coded peel off Stickers***

- Ms. Gina Butler-Galliera commented that the 4" stickers would be too large to be attached to the vaccine vials.

- Mr. Ron Filipski asked if the stickers need to be on both the vial and the packaging. Dr. Weniger responded by stating that this issue must be decided by the FDA. However, his preference would be that the sticker be attached to the vial to minimize confusion and errors.

- Ms. Carol Krueger asked pharmaceutical manufacturers if they were aware of stickers on controlled substances. Ms. Butler-Galliera stated that some SmithKline Beecham products have detachable stickers but no bar codes.

- Dr. Weniger raised the issue of stickers on multi-dose vials. He explained that more than one sticker must be attached to these vials. He suggested several possibilities to ameliorate the problem such as breaking the barcode in half or in smaller segments or using the multi-lined barcode method.

- Mr. Filipski asked if we could get the same information in less space.

- Ms. Cindy Dickson suggested we explore DataMatrix, which is a two-dimensional matrix symbology that is printable on-line and is smaller in dimension. Dr. Weniger stated that he was not familiar with this type of symbology, but thought it was an option to explore. Ms. Dixon also noted that the DataMatrix can be applied to the vaccine vial and the existing bar code system can be utilized for the secondary, or outside packaging.

- Dr. Weniger suggested that we further examine the DataMatrix system and the costs of the equipment to read this coding system.

Comments on the prototype ***Uniform Vaccine Administration Record***

- Mr. Rosofsky asked if there was a need to place the “age” field on the form since the form included fields for the “date of birth” and “date given”. Dr. Weniger stated that the

"age" field allowed the provider to quickly report the age then to calculate each age. However, Dr. Weniger agreed that the space provided for the "age" field can be shrunk.

- Dr. Weniger asked participants if they objected to the international method for the "date given" field. No one objected to this method.

- Ms. Krueger advised that the manufacturer field be blank due to the growing number of vaccine manufacturers. In addition, she stated that the fax copy of this form may be hard to read due to the small font size. It was also suggested by VISI respondents that circling the manufacturer may be easier rather than checking off the small boxes provided.

- Ms. Katie Maher asked how the Uniform Vaccine Administration Record will be disseminated. Dr. Weniger suggested various methods of dissemination including publishing this document or posting the form on the internet. He also stated that using this form would be voluntary.

- Participants made many suggestions to improve the form. One participant advised that we include "intranasal" under the "Site" field. VISI participants also agreed that we add the option of "County" under "Source".

- Other comments included eliminating "Patient/Parent/Guardian" for each record since the explanation is listed on the bottom of the form. Another suggestion was to change "Publ. Date of VIS" to "VIS Pub. Date" to save space. Still another suggestion by participants included moving the space for the sticker to the left of the page, thus providing more space for other fields. Another suggestion was that the order of asking for data on the form (from left to right) coincide with the order with which information is provided on the Vaccine Information panel (see below), or vice-versa.

Comments on the prototype ***Vaccine Information Panel***

- A suggestion for changes to the prototype information box for the secondary (cardboard) vaccine packaging was to provide "dosing" information before "volume" information, and generally to list data in the order of most common to least common need for the information. There were no other major suggestions. There seemed to be consensus this was a useful idea.

Comments on the prototype ***Manufacturer Abbreviations***

- Dr. Weniger asked manufacturers if they were content with their abbreviations Merck representatives suggested that we replace "MSD" with "MRK", since the abbreviation is widely recognized and used in their business communications.

- Dr. Weniger also suggested that the list of manufacturer abbreviations could routinely be

printed on the back of the Uniform Vaccine Administration Record, and that every issue of ths UVAR have the date of the version printed on it somewhere..

Comments on the prototype ***Vaccine Abbreviations***

- Dr. Weniger explained the rationale for standardizing on three-letter, all-capital abbreviations for each antigen, as the Europeans have drafted, except for "grandfathering" commonly and widely used abbreviations, such as MMR instead of "MEA-MUM-RUB". He also explained the proposed use of lower case letters to make important distinctions among different vaccines for the same diseases. For example, "CHLo" identifies the oral cholera vaccine and "CHLi" represents the inactivated cholera vaccine. But he indicated that it would defeat the practical purpose of using abbreviations to allow them to get long enough to be able to distinguish, for example, different types of HIB vaccine (e.g.,, HbOC, PRP-OMP, PRP-T, PRP-D). Thus, we should not demand or expect too much specificity in these abbreviations.

- Ms. Maher asked if the HL7 codes connected to CPT codes. Dr. Weniger explained that the HL7 codes were developed by the CDC for electronic transmission of immunization registry information, and were not related to CPT codes.

- Mr. Del Carvell thought that the list of vaccine abbreviations were very helpful because he encounters many phone calls regarding vaccines with unknown names received by immigrants trying to document their immunization histories. Dr. Weniger agreed that this table may be very useful if it results in international standardization to identify vaccines and if immunization record forms worldwide began to use it along with local brandnames and vernacular names.

- Mr. Rosofsky pointed out that different units at the CDC need to coordinate with each other. He noted that the abbreviation in the new immunization schedule for rotavirus, **Rv**, is not specific enough and may be confused with abbreviations for rabies vaccine. He suggested the abbreviation, "RTV". Dr. Weniger agreed, indicating there were vaccines for other "R" diseases besides rotavirus that also might cause abbreviation confusion if **Rv** were used, including respiratory syncytial virus vaccine and Rift Valley fever vaccine. Dr. Weniger agreed that there needs to be more coordination among various divisions.

- Ms. Dickson stated that people need to be educated on the standard vaccine abbreviations.

Update on the status of the NDC Database

Dr. Weniger briefly explained the purpose of the NDC database, which is a mechanism for identifying vaccines by their 10 digit NDC number. A major problem was the variable length

of some of its first and second fields (4 or 5 digits for labeler or product fields), so that some private database services were adding an additional leading zero to the middle field. This led to unauthorized 11-digit NDC numbers that would not work in a database when searching for the NDC string. Ms. Patel reported that she is currently working on entering information into an NDC database, which will contain fields for both the official 10-digit NDC string, as well as the unauthorized 11-digit string, so that search engines would work appropriately. There were currently 105 NDC numbers entered to date.

Planning for further working group discussions

All participants agreed that there needs to be further discussions regarding the draft prototypes. Dr. Weniger relayed that the rationale for the draft prototypes will be drafted and sent to all participants in the near future.

VISI participants also agreed that the method used to schedule this conference call was convenient. In the future, Ms. Patel will email 4-5 timeslots to VISI participants, and they can select the most convenient times to schedule conference calls.

Many individuals from the state health departments stated that the working group method may be more convenient for them since they can contribute more to the initiative. However, representatives from vaccine manufacturers felt that the comments and feedback from the health departments was extremely helpful during the conference call and encouraged their representation in all aspects of the initiative.

CDC will continue to revise the prototypes according to the suggestions made during the call, and then will organize another series of conference calls on specific components of the initiative within the next few months. Participants will be notified regarding the date and times selected.

Contact

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